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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,794	03/20/2006	Terrence C. Dahl	270.PFUS	7159

25000 7590 09/21/2006

GILEAD SCIENCES INC
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FOSTER CITY, CA 94404

EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/540,794	DAHL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *59-99* is/are pending in the application.

4a) Of the above claim(s) *91 and 94.95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *59,62-64,66,68-90,92,93,96,98 and 99* is/are rejected.

7)☐ Claim(s) *60,61,65,67 and 97* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species: Invention comprising tenofovir disoproxil fumarate and emtricitabine plus a third active: Reyataz, Kaletra, or Sustiva. The species are independent or distinct because the third ingredients differ structurally and a reference reading on one of these third ingredients may not read on all three third ingredients.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, inventions comprising Reyataz, Kaletra, or Sustiva are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Attorney Hensley on 9/13/06 a provisional election was made with traverse to prosecute the invention comprising tenofovir disoproxil fumarate, emtricitabine and Sustiva, claims 59-93,96-99. Affirmation of this election must be made by applicant in replying to this Office action. Claims 94 and 95 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objection under 35 CFR 1.75(c)

Claim 65 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 65 speaks to a way to manufacture the invention and therefore does not further the claim 59 from which it depends. Note claims 59 is directed to a method of administration / treatment as opposed to a method of manufacture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59,62-64, 66,68-90,92,93,96,98,99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (USAN 2005/0197320 or 10/434130; 9/8/05). Chen teaches a method of treating HIV comprising administering to a human inflicted

with HIV a composition (tablet, capsule) comprising an imidazole phosphonate compound of formula I. See paragraphs 15-18, 476, 485, 487. Chen teaches combination therapy, which involves adding to the treatment regimen one, or more other active compounds including Sustiva (NNRTI), Emtricitabine, and /or Tenofovir disoproxil. See 507-509, 541-542, 579. Chen teaches the addition of a number of excipients such as magnesium stearate (glidant), cellulose, calcium carbonate, and starch to the composition. See paragraphs 475,485, and 487. Chen teaches administering the actives to a human in need thereof on a one time per day dosage basis. See 492 and 504. Chen does not teach the a) combination therapeutic treatment comprising all 4 actives, b) instant amounts and ratios of actives and c) a patient package comprising the actives with attached instructions for using. However, one having ordinary skill in the art would have been motivated to do this since Chen suggests HIV treatment regimens can include the simultaneous or sequential administration of one or more actives to an HIV infected patient. See USAN 2005/0197320 paragraphs 507-509. With respect to the amounts and ratios of ingredients an artisan would have been motivated to optimize the ratios and amounts. An artisan would have been especially motivated to do this because drugs are known to be highly toxic, i.e., killing healthy cells. There is nothing unobvious in having drugs in a packs with instructions. In fact, in the medical industry drugs always come with instructions as how to use them.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59, 62-64,66,68-90,92,93,96,98,99 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8,10,15-20,22-26,42-55,58 of copending Application No. 10/757141. Although the conflicting claims are not identical, they are not patentably distinct from each other because USAN '141 claims an invention for treating HIV comprising administering to a human inflicted with HIV a composition (tablet, capsule) comprising Sustiva (NNRTI), Emtricitabine, and /or Tenofovir disoproxil. USAN '141 claims the actives can be contained in a patient pack with instructions attached for use, and the amounts / ratios of actives claimed in USAN '141 overlap the instant amounts / ratios of actives. USAN '141 claims the addition of a number of excipients such as magnesium stearate (glidant), cellulose, calcium carbonate, and starch to the composition. USAN '141 claims administering the actives to a human in need thereof on a one time per day dosage

basis. USAN '141 inherently claims the instant invention. However instant invention is of a narrower scope than USAN '141 in that instant invention unlike USAN '141 does not make claim to preventing the symptoms or effects of an HIV infected subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objection

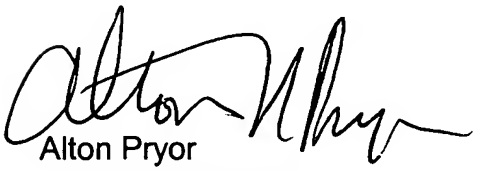
Claims 60,61,67,97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Prior art does not teach or suggest instant invention for treating HIV consisting of tenofovir disoproxil fumarate and emtricitabine as the sole actives. The prior art does not teach or suggest the instant invention comprising the ingredients and associated amounts of ingredients as recited in claims 67 and 97. Elected invention comprising Sustiva (NNRTI), Emtricitabine, and Tenofovir disoproxil fumarate is not allowable. See art rejection above.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alton Pryor
Primary Examiner
AU 1616